REMARKS

The present Amendment is in response to the Office Action dated June 26, 2003 in reference to the above-identified application. The Examiner set a shortened statutory period for reply of three (3) months, making the present Amendment due by September 26, 2003. Filed concurrently herewith is a request for a one-month extension of time so that the present Amendment is due by October 26, 2003.

In the Office Action, the Examiner articulates the restriction requirement under 35 U.S.C. §121 and §372 stating that the application does not form a single general inventive concept under PCT Rule 13.1. In particular, the Examiner identifies two groups of claims, namely, Group I (claims 1-12 and 23-27) and Group II (claims 28-37). The Examiner correctly characterizes claims 23-27 as being drawn to a product and claims 28-37 being drawn to a method of using the product.

However, Applicant notes for the record its disagreement with the Examiner's characterization that claims 1-12 are drawn to a product. This characterization also appears in reference to the rejection of the claims under 35 U.S.C. §112. While the undersigned hereby confirms that a verbal, provisional election without traverse was made to prosecute the invention of Group I (claims 1-12 and 23-27) this was made with the understanding by the undersigned that claims 1-12 thereof are use claims, as clearly recited in their preambles, and not drawn to product claims as are 23-27. In any event, affirmation is hereby made that claims 28-37 have been withdrawn from further consideration under 37 C.F.R. §1.142(b) as being drawn to a non-elected invention.

With respect to other matters in the Office Action, the Examiner has rejected each of the pending claims 1-12 and 23-27 under 35 U.S.C. §112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner maintains that the claims, as written, are confusing and are improper in their utilization of the phraseology "The use of". In this regard, Applicant respectfully disagrees and notes that the Examiner has cited no controlling authority that claims reciting "the use of" are improper. As for dependent claim 6, though, the Examiner properly noted a lack of antecedent basis for the phrase "primary treatment substance".

In an effort to fully address the Examiner's concerns under 35 U.S.C. §112(b), the Examiner will please note that Applicant has amended independent claims 1 and 2 so that they are reworded to be more in conformity with US practice, while still embodying Applicant's intended scope. Independent claim 1 encompasses the utilization of the secondary substance for the adjunct treatment of animals, wherein the secondary substance itself broadly comprises the liquid extract carried in an acceptable carrier. Independent claim 2, on the other hand, is directed to use of the secondary substance in the manufacture of a treatment product which comprises both a primary substance and the secondary substance mixed in the same carrier.

With this in mind, the Examiner will please note that amendments along these lines are made to independent claims 1 and 2 in an effort to better clarify for the Examiner their intended scope. These amendments, however, do not add any new matter to the present application and are made for clarification purposes only. As for dependent claim 6, line 2 thereof has been amended to replace the wording "treatment substance" with the wording

"chemical treatment" to provide the proper antecedent basis and to remove any concerns the Examiner may have under §112(b). All other claims of the application unchanged. In accordance with 37 C.F.R. §1.121(c), as recently revised, a claim listing accompanies these remarks which shows the above amendments and reproduces the text of all pending claims, including those withdrawn pursuant to the restriction requirement.

Turning next to the rejections over the art, claims 1-12 and 23-27 are rejected under 35 U.S.C. §102(b) as being anticipated by either US Patent No. 4,943,433 to Rudov, WIPO publication WO 91/11191 or Australian Publication No. AU A 81985/87. The Examiner maintains that each these references teaches that rye grass and antibiotics are used together. In addition to this anticipation rejection, the Examiner rejects the pending claims under 35 U.S.C. §103(a) over any of these references alone. In this regard, the Examiner maintains that it would have been obvious to use specific amounts of the extract and in the different forms called for since this is simply the choice of the artisan in an effort to optimism the desired results. However, no controlling authority is provided by the Examiner to support such a statement.

Applicant respectfully disagrees with the Examiner's rejection of the pending claims based on either §102(b) or §103(a). However, before addressing the Examiner's analysis, it may be helpful to briefly analyze the various references upon which the rejection is based.

US Patent No. 4,943,433

This patent relates to a pharmacologically effective or cosmetic substance for external application to treat e.g. acne, pimples, ulcers, cold

sores. The substance includes an extract from plants of the grass family of plants particularly cereals, the extract including juice from green components of the plants at the unjointed stage. The extract is carried in a pharmaceutically acceptable aqueous carrier or excipient, the carrier preserving the extract against deterioration and being capable of at least partial absorption by tissues so as to carry the extract to sub-surface tissues. Preferably, the carrier includes an anti-microbial agent to augment the activity of the plant extract as the primary treatment substance. The prescribed treatment regime in US 4,943,433 does not involve the use of an anti-microbial agent as a primary treatment substance and the side-effects of such a substance would not be observed under such a treatment regime.

Publication No. WO91/11191.

This publication discusses a pharmacologically effective composition for direct introduction into body tissues or vessels. The composition includes a carrier and a sterile refined extract derived from Graminaea, particularly cereal plants. Green components of the plants yield juice which is refined to comprise liquid fractions only from the juice. The composition is used in the treatment of pathological conditions including tumours and viral infections, for analgesic effects, and for the treatment of lesions. The composition may include an anti-bacterial and preservative agent, such as ethanol. It is unlikely that the skilled person would be lead to the present invention by determining that ethanol was to be used as a primary treatment substance.

Publication No. AU A 81985/87 (599725)

Here, a pharmacologically effective substance contains an extract including juice freshly derived from cereal plants at the unjointed stage of development. The substance is applied externally to treat cold sores, maintain normal skin function and aid in wound healing. Other possible uses include the treatment of colds, influenza when applied to oral mucosa or nasal mucosa, externally as well as supplementing or boosting immunity mechanisms. Preferably, the carrier includes an anti-microbial agent to augment the activity of the plant extract as the primary treatment substance. The prescribed treatment regime in AU 599725 does not involve the use of an anti-microbial agent as a primary treatment substance and the side–effects of such a substance would not be observed under such a treatment regime.

Response to Rejections under 35 U.S.C. §§ 102 & 103

The present invention, in one sense, relates to use of a secondary substance for reducing the side effects associated with a primary chemical treatment. An example is the administration of antibiotics which, when administered alone, in significant amounts and in sufficient frequencies, may have undesired side effects. The secondary substance includes a juice extract from cereal plants (claim 2), particularly rye grass (claim 1).

The Examiner asserts that each of the above citations discloses the combined use of a rye grass extract and antibiotics. Implicitly therefore, the combination so used would have resulted in the reduction of side effects in subjects treated with antibiotics. Accordingly, the Examiner is arguing, the invention can only reside in the selecting specific amount ranges of the active

substances and claiming an optimal effect is achieved in these amount ranges. The Examiner then asserts that, in any event, such selected amounts would be obvious to a skilled person who would seek to identify the best amount ranges to optimise the known effects of the combination.

The cited references describe the use of cereal plant extracts for the treatment of various maladies such as cold sores, skin lesions, tumours and viral infections, to improve a patient's immunity and as an analgesic. Accordingly, the extract is in each case being used as a primary treatment substance in which the co-administration of an antibiotic is contemplated as an option to augment the extract's primary treatment activity. There is no mention of the side effects which might follow the administration of the antibiotic as a primary treatment substance.

The side effects contemplated in the present application may be that the patient suffers rashes, nausea, etc., the normal flora in the gut is killed or the antibiotic may be found to be ineffective due to over-prescription and resistance developed by the target organisms. Such side effects, although possibly known in the medical community, were not expected under the treatment regimes described in the cited prior art where the antibiotic was only included as an optional, secondary treatment substance. Moreover, in the minor quantities and frequencies of administration of antibiotics contemplated under the cited prior art, the side effects were not and could not be expected to be evident.

Under treatment regimes disclosed in the cited prior art, it is arguable that the antibiotics, administered at levels consistent with their use as a secondary treatment substance, would not produce any side effects. In such

a situation, the plant extract would not be active as a reducer of side effects because the side effects were not suffered by the patient. Accordingly, the inventive combination of an antibiotic administered as a primary treatment substance and the plant extract as the secondary, augmentary, substance, is not disclosed or suggested in the cited prior art.

There is therefore no express disclosure nor any suggestion or reference in any of the citations which might lead a skilled person to consider, as a possibility or to try, the use of the extract as a secondary treatment substance to ameliorate the side effects caused by primary treatment substances such as antibiotics. The beneficial effects of the present invention were not previously recognised, noted or observed and the efficacy of the extract as a secondary treatment substance for side effects has only been realised with the administration of the extract following the carrying out of the primary treatment in the present invention.

Accordingly, the citations contain no disclosure which anticipates or renders obvious the claimed treatment regime comprising the use of the extract as an adjunct for reducing side effects of primary chemical treatments. The citations provide no clear and unmistakeable directions which might lead the ordinarily skilled artisan to try the inventive treatment regime and the benefit of said regime has only been realised for useful application as a result of the invention.

Based on the foregoing, Applicant submits that the present application is in complete condition for allowance, and action to that end is courteously solicited. If any issues remain to be resolved prior to the granting of this

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application, the Examiner is requested to contact the undersigned attorney for the Applicant at the telephone number listed below.

No additional claims fees are believed to be payable upon the Amendment. However, the Commissioner is hereby authorized to charge any deficiency in the required fees, or to credit any overpayment, to deposit account number 13-1940.

Respectfully submitted,

TIMOTHY J. MARTIN, P.C.

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CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing ***AMENDMENT (14 pages),*** and ***Request for a one--month Extension of Time (2 pages)*** is being deposited with the United States Postal Service as first-class mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 2231 on this 22nd day of October, 2003.

Christy L. Burbank